MANATT, PHELPS & PHILLIPS, LLP
BARRY W. LEE (Cal. Bar No. CA 088685)
bwlee@manatt.com
MISA EIRITZ (Cal. Bar No. 307513)
meiritz@manatt.com
11355 W. Olympic Boulevard
Los Angeles, CA 90064
Telephone: (310) 312-4000
Facsimile: (310) 312-4224

MANATT, PHELPS & PHILLIPS, LLP
JEFFREY S. EDELSTEIN (*pro hac vice*)
jedelstein@manatt.com
ANDREW CASE (*pro hac vice*)
acase@manatt.com
Times Square Tower
New York, NY 10036
Telephone: (212) 790-4500
Facsimile: (212) 290-4545

Attorneys for Plaintiff
Multiple Energy Technologies LLC

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

MULTIPLE ENERGY TECHNOLOGIES LLC,

Plaintiff,

vs.

HOLOGENIX LLC,

Defendant.

Case No. 2-19-CV-01483

PLAINTIFF MULTIPLE ENERGY TECHNOLOGIES LLC'S NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Filed Concurrently With:
(1) Declaration of Shannon Vissman;
(2) Declaration of Alberto Gutierrez;
(3) Declaration of Thomas Maronick;
(4) Declaration of Andrew Case;
(5) [Proposed] Order.

Date: May 20, 2019
Time: 1:30 p.m.
Courtroom: 9A
U.S. District Judge Percy Anderson

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that at 1:30 p.m. on May 20, 2019 in Courtroom 9A of the United States Courthouse located at 350 W. 1st Street in Los Angeles, plaintiff Multiple Energy Technologies, LLC ("MET") will move for a preliminary injunction against Defendant Hologenix LLC pursuant to Federal Rule of Civil Procedure 65, and the local Rules of the Central District of California. In particular, MET seeks an Order enjoining Defendant Hologenix LLC from making any statement in any forum including but not limited to statements: 1) on its website, 2) on a social media platform, or 3) to any member of the press, that either 1) states or suggests that the Food and Drug Administration ("FDA") has "approved" Hologenix's product Celliant for any use or, b) states or suggests that the FDA has made a "determination" as to whether Celliant provides any purported benefits, whether those benefits are categorized as medical benefits or "general wellness" benefits on the grounds that said statements are false and misleading.

In addition, to correct the statements that Hologenix has previously issued, MET seeks and Order that:

1) Hologenix send the following statement to each and every manufacturer that has used Celliant in its products since July 25, 2017:

"Celliant has previously claimed that its product had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. The FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits.

Please state on your website where you offer products that use Celliant, and send a notice to any consumer lists where you have sent a prior notice regarding Celliant, that: 1) prior statements that the FDA had 'approved' Celliant or made a 'determination' about its benefits were false and 2) the FDA has not approved Celliant for any purpose and has not made any determination about its purported

benefits."

2) Hologenix place the following statement on the landing page of the Celliant website, above any other text and in a font equal to or larger than any other text that appears on the website:

"Celliant has previously claimed that its product had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. The FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

3) Hologenix issue the following statement once per day on its Facebook account and its Twitter account every day until this litigation is concluded:

"Celliant has previously claimed that its product had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. The FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

4) Hologenix issue a press release with the following statement:

"Celliant has previously claimed that its product had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. The FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

5) Hologenix issue to each and every journalist that wrote an article about Celliant, including the following:

"Hologenix, LLC seeks a correction to your article of [Date] regarding Celliant. The article stated that Celliant had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. Please issue a correction noting that the FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

The Motion is based upon this Notice of Motion and Motion, the Memorandum of Points and Authorities, the declarations of Dr. Shannon Vissman,

Dr. Alberto Gutierrez, Professor Thomas Maronick, and Andrew Case, and any additional matters that the Court may consider at the time of the hearing.

Dated: April 22, 2019

MANATT, PHELPS & PHILLIPS, LLP

By: */s/ Barry W. Lee*

Barry W. Lee
Jeffrey S. Edelstein (*pro hac vice*)
11355 W. Olympic Boulevard
Los Angeles, CA 90064
Telephone: (310) 312-4000

Attorneys for Plaintiff
Multiple Energy Technologies LLC

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

STATUTES

OTHER AUTHORITIES

MEMORANDUM OF POINTS AND AUTHORITIES

PRELIMINARY STATEMENT

This case is a textbook example of precisely the sort of behavior that the Lanham Act is meant to prevent. Plaintiff Multiple Energy Technologies LLC ("MET") developed a valuable bioceramic powder that could be applied to textiles, resulting in clothing and bedding that reflect the body's heat back to it as Far Infrared ("FIR") energy. MET's proprietary, patented formulation attracted Under Armour, Inc. ("Under Armour") and American Textile, Inc. ("American Textile")—each of which entered into contracts to purchase MET's bioceramic powder to use in their products.

In order to deprive MET of the benefit of these relationships, Defendant Hologenix LLC ("Hologenix") engaged in a massive, nationwide media campaign, the centerpiece of which was a lie. Hologenix claimed that the Food and Drug Administration ("FDA") had "approved" its product, a lie so blatant that the moment this lawsuit was filed, Hologenix began to scrub its social media accounts. But Hologenix has done nothing to correct the record it had already established—that the FDA had "approved" its product.

As part of Hologenix's deceptive plan, it issued a press release stating that the FDA "determined" that Hologenix's bioceramic product was a "medical device," and that the FDA made this determination "because [the products] temporarily promote increased local blood flow at the site of application in healthy individuals." However, the FDA had made no determination about whether Hologenix's products promoted increased local blood flow. In fact, the FDA had made no determination about Hologenix's claims at all. Again, Hologenix did nothing to arrest the misinterpretation that the FDA had "determined" its product provided certain health benefits.

Articles claiming that Hologenix's product was approved by the FDA appeared shortly after this false claim was made and as recently as April 3, 2019.

To this day, Hologenix continues to mislead consumers by suggesting that the FDA has approved and made determinations regarding the benefits Hologenix's products offer.

Hologenix's campaign of deception worked. It caused American Textile and Under Armour to discontinue their relationship with MET. Both companies now use Hologenix's product, and Under Armour has spread Hologenix's false and misleading claims. The ongoing harm from Hologenix's campaign of lies has now pushed MET to the brink of extinction.

MET respectfully asks the Court to enjoin Hologenix from making any further statements regarding the FDA's approval and/or determinations about its products and to compel Hologenix to issue corrective advertising on its website and social media accounts and to any media outlet that spread its false and misleading claims.

FACTUAL BACKGROUND

I. MET Secures Contractual Arrangements With Under Armour and American Textile

In late 2014, MET began discussing an agreement with Under Armour to supply its patented formula of bioceramic powder, branded Redwave®, to Under Armour for use in sleepwear. (Declaration of Dr. Shannon Vissman in Support of Plaintiff's Motion for Preliminary Injunction ("Vissman Decl.") ¶ 2.) On January 15, 2015, MET and Under Armour signed a Material Transfer Agreement. (Vissman Decl. ¶ 3.) In January 2017, Under Armour launched a line of athletic recovery sleepwear using Redwave at CES, a trade show in Las Vegas. (Vissman Decl. ¶ 4.) The launch was covered by *Time* magazine, among others. (Declaration of Andrew Case in Support of Plaintiff's Motion for a Preliminary Injunction ("Case Decl.") Ex. A.) After the successful launch, and based on the response at CES, MET and Under Armour began to negotiate a three-year agreement under which Under Armour would pay MET a projected $2,500,000 per year to allow

Under Armour to be the exclusive manufacturer of sleepwear incorporating Redwave, and would make a separate payment for each kilogram of Redwave used. (Vissman Decl. ¶ 5.)

Under Armour was not MET's only major client. Beginning in 2015, MET and American Textile entered into a series of agreements whereby MET would supply American Textile with Redwave for use in bedding. These agreements included a June 3, 2015 Material Transfer Agreement and a May 4, 2016 Evaluation and Supply Agreement. (Vissman Decl. ¶ 6.) The Evaluation and Supply Agreement included an option for American Textile, which it exercised on April 3, 2017, triggering a series of automatic renewals until either party terminated. (Vissman Decl. ¶ 7.)

Thus, by mid-2017, MET had agreements with two major manufacturers to supply them with Redwave for incorporation into their products and was in discussions with other major manufacturers as well. (Vissman Decl. ¶ 8.)

II. Hologenix Claims the FDA "Approved" Its Competing Product and "Determined" Its Benefits

Hologenix manufactures a competing bioceramic branded Celliant®. While Redwave is manufactured as a powder, to be applied onto fabric by a manufacturer, Celliant is manufactured as a fiber that is woven into fabrics. (Vissman Decl. ¶ 9.) On July 25, 2017, Hologenix sought to promote its brand by issuing a press release stating that the FDA had "determined" that Celliant products "are medical devices and general wellness products." (Case Decl. Ex. B.) The press release claimed that "[a]ccording to the FDA, Celliant products were determined to be medical devices ***because they temporarily promote increased local blood flow at the site of application in healthy individuals***." (*Id.* (*emphasis added*).) The press release did not cite to any FDA document or provide any statement from the FDA in support of its claims that the FDA had made a determination that Celliant increased local blood flow. As demonstrated below, the FDA made no such determination about

Celliant. The press release was false. Hologenix followed up its false press release with a campaign in which it claimed—on its social media platforms and in major publications—that the FDA had "approved" Celliant. (Case Decl. Exs. C–F.) These claims too were patently false.

Hologenix's deceptive claims—that the FDA had "approved" its product and that the FDA had made a determination about Celliant's benefits—materially affected the decisions of manufacturers and consumers to reject MET's product. As but one example, American Textile told MET that Hologenix was touting its "FDA approval for Celliant," and asked how MET could compete against that claim. (Vissman Decl. ¶ 10.)

Hologenix's press release and its campaign had the desired effect on Under Armour and, ultimately, American Textile. Although MET and Under Armour had been negotiating during the first half of 2017, in June 2017 Under Armour went silent, and soon after the Hologenix press release came out, Under Armour terminated the exclusivity provisions of its agreement with MET. (Vissman Decl. ¶ 11.) In a conversation with a MET executive, an American Textile executive said that Under Armour switched to Hologenix specifically so that Under Armour could use Hologenix's promotional statements. (Vissman Decl. ¶ 12.) American Textile followed suit, terminating its agreement with MET, switching from Redwave to Celliant. (Vissman Decl. ¶ 13.)

III. Hologenix Continued to Make False and Misleading Claims

After issuing the July press release, Hologenix continued to make the false claim that Celliant had been "approved" by the FDA. But the FDA has not approved Celliant: FDA approval is a years-long process, and the FDA publicly discloses when a product is approved. Hologenix knows that it lied about FDA approval, admitting as much in its Answer, and since the filing of this action, straining (but failing) to erase its false statements from the Internet. Moreover, Hologenix claimed, and continues to claim, that the FDA has "determined" that

Celliant provides certain benefits, when the agency has done no such thing. Even Hologenix's most conservative claim—the claim on the landing page of celliant.com, "FDA Determined Medical Device and General Wellness Product"—has been presented in a manner that misleads customers into thinking the FDA has found that Celliant offers health benefits, as evidenced by the consumer survey commissioned by MET.

A. Hologenix Made the Literally False Claim That the FDA "Approved" Celliant

On its social media platforms, Hologenix boasted repeatedly that the FDA had "approved" Celliant. On July 31, 2017, it issued a statement via Twitter that read, "What are you waiting for? Celliant is now FDA-approved, get your products today!" (Case Decl. Ex. C.) That same day, it issued a similar statement via Facebook. (Case Decl. Ex. D.) Hologenix continued to issue public statements on social media touting the FDA's approval by making claims under the hashtag "#FDAapproval." (Case Decl. Exs. E–F.)

The use of the term "approval" was no accident; it was clearly intentional. Hologenix's co-founder and co-president, Seth Casden, discussed "[t]he approval that we have now" with the *Huffington Post* on August 28, 2017. (Case Decl. Ex. G.) Nor was there any confusion about what FDA "approval" meant. In the article in which Casden spoke of the "approval," the journalist went on to describe the significance of FDA approval:

> In order to protect the consumer, the F.D.A. expresses that to make health related claims, companies must fulfill certain criteria proven by scientific research prior to being approved. A topic as serious as one's health puts pressure on the wellness industry which is why companies like Hologenix spend years working towards the necessary F.D.A. approval.

Hologenix wrote a blog post touting and linking to the *Huffington Post* article that falsely claims Celliant went through the years-long FDA approval process; that post remains on its website to this day. (Case Decl. Ex. H.) In the

September/October 2017 issue of the trade publication *Textile Insight*, Casden said, in an article that was headlined "Perseverance Pays Off for Celliant with ***FDA Approval***," that "[t]here's been an overwhelming positive response to the ***FDA approval***." (Case Decl. Ex. I) (emphasis added).

Hologenix was hardly shy about issuing and endorsing false statements that the FDA had approved Celliant. In fact, articles using some version of the term "FDA Approved" or "FDA Approval" were published by *Inc.* on February 22, 2018, by *Hunker* on June 27, 2018, by *Shape* on July 18, 2018, by *WWD Digital Daily* on July 18, 2018, by *Gear Patrol* on August 27, 2018, by *Talking Points Memo* on August 31, 2018, and on multiple vendor websites. (Case Decl. Exs. J–Q.)

The FDA has not approved Hologenix's product. Once this lawsuit was filed, Hologenix began deleting tweets and Facebook posts, leaving behind a collection of error messages where it had once boasted of its #FDAapproval. (Case Decl. Exs. T–W.) But these statements had been online, available, and influencing customers and manufacturers for months already. And this purge did not change the false message Hologenix and its partners have been sending, and continue to send as recently as three weeks ago. On April 3, 2019, when Under Armour announced yet another line of apparel using Celliant, the product was promoted in at least two articles touting the (false) fact that Celliant had been "approved" by the FDA. (Case Decl. Exs. R–S.)

B. Hologenix Continues to Make False and Misleading Claims That the FDA Has Determined Celliant Provides Certain Benefits

In addition to falsely claiming that the FDA had "approved" Celliant, Hologenix claimed as early as July 2017 that the FDA had made a determination about Celliant's benefits. In the original press release, Hologenix claimed that the FDA had "determined" that Celliant products were medical devices "because they temporarily promote increased blood flow at the site of application in healthy

individuals." (Case Decl. Ex. B.) But even if the FDA had told Hologenix that it may consider Celliant a Class I medical device or a "general wellness" product (although MET has seen no supporting evidence that the FDA did so), all that means is that the product is not subject to FDA approval—it is not a determination of the underlying claims about the product's benefits.

Despite this, Hologenix claimed—and continues to claim—that the FDA not only made a determination that Celliant is a "medical device" and that it is a "general wellness product," but that the FDA ***determined that Celliant offers certain benefits***. As MET's FDA expert explains, this is not a determination that the FDA makes regarding Class I medical devices or general wellness products. And as MET's consumer survey demonstrates, the promotional statements (still on the Hologenix website today) mislead consumers into believing that the FDA has made a determination regarding the benefits of Celliant.

1. *Former FDA Director Concludes That Hologenix's Claims Are False and Misleading*

MET has engaged Dr. Alberto Gutierrez, a recognized expert who spent decades at the FDA working on approvals and determinations of medical devices.[1] While he has not reviewed the correspondence between the FDA and Hologenix—Hologenix has refused to provide it and the FDA has not responded to a Freedom of Information Act ("FOIA") request—he has set forth the criteria under which the FDA approves and makes determinations about product benefits, and his conclusions are that the FDA has not made a determination about the underlying benefits of Celliant.

According to Dr. Gutierrez, the statements that Celliant has been "approved" by the FDA and that it is "FDA Approved" are "literally false." (Declaration of Dr.

[1] Dr. Gutierrez is the former director of the FDA's Office of In Vitro Diagnostics and Radiological Health. In his 25 years at the FDA, he was personally involved in the process by which the FDA responds to requests for information and the process by which it approves medical devices for registration and listing.

Albert Gutierrez in Support of Plaintiff's Motion for Preliminary Injunction ("Gutierrez Decl.") ¶ 9.) This fact can be verified because the FDA publishes a list of medical devices it has approved, cleared, or authorized, and the list published on the FDA website does not include Celliant or any Hologenix product. (Gutierrez Decl. ¶¶ 7–8.)

The FDA does have a process whereby a company may submit a request for information (called a "513(g) Request for Information" or also, here, a "513(g) Request") regarding whether a particular product would be a "medical device" subject to registration and listing. (Gutierrez Decl. ¶ 10.) The FDA does not respond to a 513(g) Request for Information by making any determination about the ***underlying benefits*** of a particular product. (Gutierrez Decl. ¶ 11.) Instead, the FDA responds to such a request based only on claims the manufacturer wishes to make, which include the product's intended use. (Gutierrez Decl. ¶ 12.)

If a manufacturer wants to make claims about a product's medical benefits, other than ones that generally fall under "wellness," the FDA would typically respond to a 513(g) Request for Information by stating that the product is a "medical device" that falls within a specific regulation and classification, and stating whether the product and those claims can be marketed before the test is approved, cleared, or authorized by the FDA. (Gutierrez Decl. ¶ 15.) But, as the FDA has stated in written guidance, if a product's "intended use" is for general health and well-being, it may be classified as a Class I medical device or a "general wellness" product, and such products are not subject to registration and listing. (Gutierrez Decl. ¶¶ 16–17.) The guidance for general wellness products states that a product is classified as a "general wellness" product when it "has (1) an ***intended use*** that relates to maintaining or encouraging a general state of health or a healthy activity or (2) an ***intended use*** that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important

role in health outcomes for the disease or condition." FDA, *General Wellness: Policy for Low Risk Devices (July 29, 2016)*. Whether the FDA responds to a 513(g) Request by stating that a product is a medical device subject to registration or listing, or whether it responds to such a request by stating that a product appears to be a Class I medical device or a "general wellness product" based on its intended uses, the FDA makes ***no determination*** as to how the product functions or whether it provides the purported benefits in response to a 513(g) Request. (Gutierrez Decl. ¶ 18.)

Simply put, the claim that the FDA has "approved" Celliant is literally false. (Gutierrez Decl. ¶ 9.) Likewise, claims that the FDA has "determined" that Celliant provides benefits—for example that it promotes increased blood flow to an applied area—are false when read in context. Even if the FDA responded to a 513(g) Request for Information by Hologenix by stating that Celliant is a "general wellness product" (for which FDA has enforcement discretion over all regulatory requirements) or that it is a "medical device" with information of what are the relevant regulatory requirements (registration and listing often being one, and premarket review sometimes being another), such a response does not include any determination regarding Celliant's purported benefits. (Gutierrez Decl. ¶ 19.)

2. *A Consumer Survey Confirms That Hologenix's Claims Are False and Misleading*

MET has engaged Thomas Maronick, DBA, JD, an Emeritus Professor of Marketing at Towson University in Towson, Maryland, to conduct a survey regarding consumer perceptions of Hologenix's statements regarding the FDA.[2] Dr.

[2] Dr. Maronick served as the Director of Impact Evaluation in the Bureau of Consumer Protection at the Federal Trade Commission for 17 years. He was responsible for the evaluation of research submitted by firms being investigated by the Commission and for the design and implementation of all consumer research undertaken by the Bureau during that period. (Declaration of Thomas. Maronick, DBA, JD, in Support of Plaintiff's Motion for Preliminary Injunction ("Maronick Decl.") ¶ 6.)

Maronick designed an online consumer study in which one group of consumers was shown the landing pages of the Celliant website (which features the claim that Celliant is an "FDA Determined Medical Device and General Wellness Product" before touting certain benefits) and the control group was shown the same webpages without the "FDA Determined" language. (Maronick Decl. ¶ 9.)

Consumers who were shown the "FDA Determined" language not only thought that the FDA had determined that Celliant was a general wellness product, but 68.5% of them also thought that the FDA had made a determination about the benefits that one can get from Celliant. Only 21.2% of those who were shown the webpage without the "FDA Determined" language thought that the FDA had made a determination about the benefits of Celliant; this is a difference of 47.3 percentage points. (Maronick Decl. ¶ 11.)

When asked an open-ended question about whether the FDA had made a determination about the benefits of Celliant, 43.4% of those who had seen the statement "FDA Determined Medical Device and General Wellness Product" wrote in that the FDA had made such a determination. (Maronick Decl. ¶ 10.) Answers to this question ranged from statements that the FDA had made a determination that the product improved general wellness to statements that the FDA had conducted its own tests or approved the product. (*Id.*) When offered the opportunity to select whether or not the FDA had determined that Celliant increased circulation, helped cell recovery, regulated body temperature, improved sleep, or improved athletic performance, respondents who had seen the "FDA Determined" language responded that the FDA had made such a determination, at percentage levels ranging from 22 to 39 percentage points higher than those of the control group. (Maronick Decl. ¶¶ 11–16.)

As Dr. Maronick concluded, "the 'FDA determination' claim is seen as an indicator that the FDA has tested and/or approved the claims made about the product." (Maronick Decl. ¶ 18.) And FDA determination matters: As Dr.

Maronick found, "the vast majority of respondents in both the Test Block and the Control Block are much more likely to buy performance enhancing fabric if they believe the FDA has 'determined' the benefits claimed." (Maronick Decl. ¶ 17.)

IV. Hologenix's Misleading and False Claims Caused Substantial Harm, Putting MET's Viability at Risk

When Hologenix first claimed that the FDA had "approved" Celliant, and then that the FDA had "determined" that it provided certain benefits, MET set out to verify the claims before alleging that Hologenix was making false and misleading statements. Neither the press release nor any public statement from Hologenix cited to a public FDA document. The FDA's publicly available list of medical devices does not include Celliant. But, proceeding with the same caution that it used when it declined to make misleading claims about its own product, MET sought confirmation from the FDA.

On July 13, 2018, MET filed two FOIA requests with the FDA seeking all information about the 513(g) Requests that Hologenix had made to the FDA. (Vissman Decl. ¶ 14, Exs. A–B.) On October 16, 2018, MET requested expedited treatment of the requests. (Vissman Decl. ¶ 15, Exs. C–D.) The FDA denied the requests for expedited treatment for both requests on October 26, 2018. (Vissman Decl. ¶ 16, Exs. E–F.) With no prospect of obtaining any confirmation from the FDA regarding Hologenix's claims, but with confirmation through the FDA website that the FDA had not "approved" Celliant and that responses to 513(g) Requests do not include any "determination" of a product's benefits, MET proceeded to file this lawsuit.

The loss of the Under Armour and American Textile contracts devastated MET, and if Hologenix's conduct continues unabated, it will drive MET out of business. In 2017, Under Armour ceased doing business exclusively with MET based on Hologenix's false statements, a significant blow. In 2018, American Textile and Under Armour ceased to do any business with MET. MET, unable to

compete given the power of Hologenix's false statements, no longer has any customers or prospects for customers in this space. All of its key personnel have left the company.

Hologenix's deception continues. In early April 2019, Under Armour announced a new line of clothing, "RUSH," to incorporate Celliant, and press coverage of the launch reiterated the claims that Celliant had been "approved" by the FDA. A *Forbes* article published on April 3, 2019, falsely described Celliant's "FDA approval as an infrared wellness device." (Case Decl. Ex. S.) Hologenix's deceptive and misleading campaign must be enjoined.

ARGUMENT

I. Preliminary Injunction Standard

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Marlyn Nutraceuticals, Inc. v. Mucos Pharma*, 571 F.3d 873, 877 (9th Cir. 2009) (*quoting Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). "[T]he elements of the preliminary injunction test are balanced, so that a stronger showing of one element may offset a weaker showing of another." *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011).

Here, each of the four factors weighs strongly in favor of a preliminary injunction. Success on the merits is virtually guaranteed. The damage to MET is precisely the type of irreparable injury that injunctive relief is designed to prevent. And both the public interest and the balance of hardships weigh in favor of the injunction, as the law recognizes no hardship in requiring a defendant to stop violating the law. *See Phillip Morris USA Inc. v. Shalabi*, 352 F. Supp. 2d 1067, 1075 (C.D. Cal. 2004) (granting a permanent injunction where relative hardships weighed in plaintiff's favor, as "Plaintiff is only seeking to enjoin illegal activity").

II. All Four Elements Tip Decidedly in Plaintiff's Favor

A. Plaintiff Is Likely to Succeed on the Merits of Its False Advertising Claim

Section 43(a) of the Lanham Act prohibits "[a]ny person who, on or in connection with any goods or services ... uses in commerce any ... false or misleading description of fact, or false or misleading representation of fact." 15 U.S.C. § 1125(a). The Act "allows one competitor to sue another if it alleges unfair competition arising from false or misleading product descriptions." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 106 (2014).

A Lanham Act claim for false advertising has five elements: "(1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products." *Skydive Arizona, Inc. v. Quattrocchi*, 673 F.3d 1105, 1110 (9th Cir. 2012). All five elements are satisfied here.

1. *Hologenix's Statements Are False Commercial Claims*

To constitute "commercial advertising or promotion," a statement must be "(1) commercial speech; (2) by the defendant who is in commercial competition with the plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services." *Newcal Indus., Inc. v. Ikon Office Sol.*, 513 F.3d 1038, 1054 (9th Cir. 2008) (*quoting Coastal Abstract Service, Inc. v. First American Title Insurance Co.*, 173 F.3d 725, 735 (9th Cir. 1999)). The statement need not be part of a "classic advertising campaign" but may be more "informal types of 'promotion.'" *Id.* Social media campaigns can violate the Lanham Act if they are

used to promote products. *See Wonderland Bakery Inc. v. Wonderland Custom Cakes, LLC*, No. 13-00076 2013 WL 12123693 (C.D. Cal. May 6, 2013). Hologenix's social media statements and its claims on its website satisfy the commercial advertising prong of the first element.

A false statement is one that is either "literally false, either on its face or by necessary implication, or … literally true but likely to mislead or confuse consumers." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997). Before a claim can be determined to be "literally false," it "must … be analyzed in its full context." *Id.* If a claim's meaning is false when the claim is reviewed "in its entirety, rather than examining the eyes, nose, and mouth separately and in isolation from each other," that claim is "literally false" by necessary implication. *Id.* (*quoting Cuisinarts, Inc. v. Robot–Coupe Int'l Corp.*, No. 81-731, 1982 WL 121559, *2 (S.D.N.Y. June 9, 1982)).

Even a claim that is not "literally false" may be false because it is "likely to mislead or confuse consumers." *Southerland Sod*, 108 F.3d at 1139. When a plaintiff claims that advertising is misleading, "proof that the advertising actually conveyed the implied message and thereby deceived a significant portion of the recipients becomes critical." *William H. Morris Co. v. Grp. W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995), *supplemented sub nom. William H. Morris Co. v. Grp. W, Inc.*, 67 F.3d 310 (9th Cir. 1995). Such evidence is produced "usually in the form of market research or consumer surveys, showing exactly what message ordinary consumers received from the ad." J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:55 (4th ed. 1996). As set forth below, Hologenix's statements are literally false, false by necessary implication, and misleading.

a. The "FDA-Approved" Statements Are False

Defendant has admitted that its campaign touting Celliant's "#FDAapproval" was literally false. *See* Defendant's Answer to Complaint and Counterclaim, Doc.

19 ("Ans.") ¶ 4 ("Defendant admits that ***the FDA has not 'approved' the Product***") (emphasis added). While Hologenix now contends "on rare occasions, it erroneously noted that the Product was approved by the FDA," the social media posts and public statements by its CEO were neither rare nor erroneous. Ans. ¶ 3. Despite the fact that Hologenix has done its best to erase these posts in the past few weeks, its campaign had already sent the message to consumers and media outlets, and it has done nothing to correct the false record that it promoted and nurtured—articles continued to appear touting Hologenix's FDA "approval" as recently as April 2019. (Case Decl. Ex. S.)

Celliant has not been "approved" by the FDA, and Hologenix's multiple claims that it has been are literally false. And because when "the advertisement is literally false, a violation may be established without evidence of consumer deception," for the literally false statements, no consumer survey evidence is required to establish success on the merits. *Mut. Pharm. Co. v. Ivax Pharm., Inc.*, 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006) (*quoting Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 273 (4th Cir. 2002)).

b. Hologenix's "FDA-Determined" Statements Are False by Necessary Implication and Misleading

Hologenix has made continued claims that the FDA has determined that Celliant provides the benefits that Hologenix claims. These claims began with the initial press release, in which Hologenix claimed that the FDA determined its products were medical devices "because they temporarily promote increased blood flow at the site of application in healthy individuals." (Case Decl. Ex. B.) When Hologenix's claim is read "in its entirety," it necessarily implies that the FDA had determined the benefits of Celliant. *Southland Sod*, 108 F.3d at 1139. For example, another manufacturer of bedding using Celliant, Yaasa, cites to the initial press release and describes its conclusions thusly: "After the Food and Drug

Administration ***clinically tested*** Celliant products, they ***deemed*** the technology increases blood flow to areas that came in contact with the skin." (Case Decl. Ex. X.) Hologenix's statements are false by necessary implication because they state that the FDA has made a determination regarding the benefits of Celliant. Like all false claims, claims that are false by necessary implication require no consumer survey evidence to establish success on the merits. *Mut. Pharm. Co.*, 459 F. Supp. 2d at 933.

Equally significant, MET's consumer survey shows that the statements are misleading. Nearly 70% of the consumers who were shown the Celliant webpage concluded that the FDA had made a determination about Celliant's benefits, for a net confusion rate that was nearly 50 percentage points higher than for those who were shown the webpage without such language. And when asked what benefits the FDA had specifically determined, consumers who saw the "FDA Determined" language concluded that the FDA had made specific determinations about specific benefits at rates 26 to 40 percentage points higher than rates applicable to those who had not seen the language. Courts rely on rates lower than this to conclude that "actual confusion has been shown," which is "dispositive that a likelihood of confusion exists." *Anheuser-Busch, Inc. v. Customer Co.*, 947 F. Supp. 422, 425 (N.D. Cal. 1996) (issuing preliminary injunction based on consumer survey results and collecting cases showing that a net 15-20% confusion rate on such surveys is sufficient to prove likelihood of confusion).

2. *The Statements Actually Deceive Consumers and Are Material*

For the claims that are literally false (that Celliant is "FDA Approved") and the claim that is false by necessary implication (that the FDA has "determined" that Celliant promotes blood flow), actual deception and materiality are presumed. *See FLIR Sys., Inc. v. Sierra Media, Inc.*, 903 F. Supp. 2d 1120, 1129 (D. Or. 2012) (*quoting Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 157 (2d Cir. 2007)) ("When an advertisement is shown to be literally or facially false, consumer

deception is presumed, and the court may grant relief without reference to the advertisement's actual impact on the buying public.").

For the claims that are misleading—that the FDA has made determinations about Celliant's benefits—Dr. Maronick's study provides evidence that consumers have been deceived and that the deception will influence their purchases. (Maronick Decl. ¶¶ 10–19.) Evidence from consumer surveys can satisfy the deception and materiality claims in a Lanham Act case. *See Southland Sod*, 108 F.3d at 1140 (relief is available under the Lanham Act if it can be shown that an advertisement has misled, confused, or deceived the public, and reactions of the public are typically tested through the use of consumer surveys).

3. *The Statements Entered Interstate Commerce and Are Causing Actual Injury*

Hologenix has made its claims on social media platforms, on its own website, and in national media campaigns. Each of these campaigns is national in scope, satisfying the interstate commerce prong of a Lanham Act claim. *See TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 829 (9th Cir. 2011) ("A plaintiff bringing a false advertising claim must also show that defendant caused its false or misleading statement to enter interstate commerce . . . but this is virtually automatic for websites."). And MET has been injured; it has already lost its two largest clients because of Hologenix's false advertising. As set forth in detail below, the future harm that could come from Hologenix's continued false claims would be irreparable, easily satisfying the fifth element of a Lanham Act claim. *Stuhlbarg Int'l Sales Co. v. John D. Brush & Co.*, 240 F.3d 832, 838 (9th Cir. 2001) (noting that irreparable harm could stem from lost contracts and customers).

B. Plaintiff Is Likely to Suffer Irreparable Harm

A plaintiff that establishes a likelihood of success on the merits must also show that irreparable injury is likely absent an injunction. *Winter*, 555 U.S. at 20. The Ninth Circuit has recognized that in *Winter*, the Supreme Court "did not reject

the 'sliding-scale' formulation, under which relief is sometimes awarded 'based on a lower likelihood of harm when the likelihood of success is very high.'" *Greater Yellowstone Coal. v. Timchak*, 323 F. App'x 512, 514 n.1 (9th Cir. 2009) (quoting *Winter*, 555 U.S. at 51, Ginsburg, J. *dissenting*). While after *Winter*, a preliminary injunction may no longer issue when irreparable harm is merely possible, "the 'sliding scale' approach to preliminary injunctions remains valid." *McCormack v. Hiedeman*, 694 F.3d 1004, 1016 n. 7 (9th Cir. 2012).

Defendant's false advertising is irreparably harming MET in several ways. MET has nearly closed its doors because Redwave is viewed as inferior to Hologenix's "FDA approved" and "FDA determined" product. (Vissman Decl. ¶ 17). Courts routinely hold that "[t]he threat of being driven out of business is sufficient to establish irreparable harm." *Am. Passage Media Corp. v. Cass Commc'ns, Inc.*, 750 F.2d 1470, 1474 (9th Cir. 1985); *see also Doran v. Salem Inn, Inc.*, 422 U.S. 922, 932 (1975) (holding that "a substantial loss of business and perhaps even bankruptcy" constitutes irreparable harm sufficient to warrant interim relief). The Northern District of California held recently that "credible assertions" that without an injunction a business may fail "are sufficient to constitute irreparable harm." *hiQ Labs, Inc. v. LinkedIn Corp.*, 273 F. Supp. 3d 1099, 1105 (N.D. Cal. 2017). Even if MET were to survive, it has already lost two clients, and is likely to lose prospective clients because of Hologenix's false claims, which constitutes irreparable harm because "[e]vidence of threatened loss of prospective customers or goodwill certainly supports" finding irreparable harm. *Stuhlbarg Int'l.*, 240 F.3d at 841.

And while Hologenix has been making false claims since 2017, the harm to MET has progressed over time; it is now likely that such harm will be irreparable if not checked. As the Ninth Circuit has held, "waiting to file for preliminary relief until a credible case for irreparable harm can be made is prudent rather than dilatory." *Arc of California v. Douglas*, 757 F.3d 975, 991 (9th Cir. 2014)

(reversing a district court decision that denied a preliminary injunction based on conduct that began two years before the lawsuit, but which had continued to cause "ongoing, worsening injuries" ever since). Here, and much like in *Arc*, the threat of irreparable harm came to fruition after American Textile terminated its contract in 2018 and Under Armour began repeating the claims that Celliant had been "approved" by the FDA in April 2019. MET lost concrete business relationships and profit when American Textile and Under Armour terminated their contracts with MET. And here, MET sought an explanation from the FDA that would confirm what it had determined about Celliant. (Vissman Decl. ¶¶ 14–16.) When a party conducts a "cautious investigation" prior to bringing a lawsuit, the time spent on that investigation does not necessarily constitute delay. *Disney Enterprises, Inc. v. VidAngel, Inc.*, 869 F.3d 848, 866 (9th Cir. 2017). Under Armour has launched a new product line using Celliant this month, and press coverage has boasted of its FDA "approval." (Case Decl. Ex. S.) Meanwhile, MET has no customers and has no current prospect of finding any so long as Hologenix's false and misleading claims continue. (Vissman Decl. ¶ 18.)

Here, Hologenix and MET sell similar products, and FDA approval or an FDA determination regarding the health benefits of one company's product provides that company with an immediate marketing advantage. After all, both Under Armour and American Textile represented to MET that such claims were important to their campaigns. (Vissman Decl. ¶ 19.) Hologenix created a likelihood of irreparable injury when it relied on these false statements to increase its customer base. And the efforts that Hologenix has taken to tout its product as FDA "approved" and "determined" underscore just how valuable such a phrase is.

C. Balance of Hardships Favors an Injunction

Barring Hologenix from making its false and misleading claims will not harm Hologenix, but will merely level the playing field between competitors and provide the public with truthful information. "Indeed, there is no harm to a

defendant from an injunction which prevents continuing dissemination of false statements." *POM Wonderful LLC v. Purely Juice, Inc.*, No. 07-02633, 2008 WL 4222045, at *16 (C.D. Cal. July 17, 2008) *aff'd*, 362 Fed. App'x 577 (9th Cir. 2009). Therefore, requiring a defendant to refrain from using false statements in the marketplace poses little danger of prejudice; "[s]uch requested relief poses little, if any, harm to the defendant." *Id.* (internal citations omitted) (quoting *Sun Microsystems, Inc. v. Microsoft Corp.*, 87 F. Supp. 2d 992, 998 (N.D. Cal. 2000)).

Here, Defendant made a conscious decision to market its product based on false and misleading information. It knowingly used terms like "FDA approved" and "FDA determined" in various circumstances in order to accomplish its marketing strategy. Furthermore, Hologenix continues to make these false statements to the public in pursuit of profit. There is no legitimate argument that Defendant can lodge regarding the hardship of abandoning and correcting deceitful advertising targeted to actual and potential customers, business partners, and the public. Consequently, the balance of hardships weighs in favor of granting a preliminary injunction.

D. An Injunction Is in the Public Interest

It is in the public interest for Hologenix to be enjoined from further false advertising and to correct those false statements it has already made. "[T]he most basic public interest at stake in all Lanham Act cases [is] the interest in prevention of confusion, particularly as it affects the public interest in truth and accuracy." *Warner Bros. Entm't vs. Glob. Asylum, Inc.*, No. 12-9547, 2012 WL 6951315, at *23 (C.D. Cal. Dec. 10, 2012) *aff'd sub nom. Warner Bros. Entm't v. Glob. Asylum, Inc.*, 544 Fed. App'x 683 (9th Cir. 2013). Consumers make assumptions about the quality of goods and services, standards, warranty, and customer service based on the seller of a product. *Qualitex Co. v. Jacobson Prod. Co.*, 514 U.S. 159, 163-64 (1995). And the public has a protectable interest in being honestly informed as to the seller of a product and the quality of goods. *AT&T Corp. v. Vision One Sec.*

Sys., No. 95-0565, 1995 WL 476251, at *7 (S.D. Cal. July 27, 1995); *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, No. 14-137, 2014 WL 2002126, at *13 (W.D. Penn. May 15, 2014), *aff'd* 774 F.3d 192 (3d Cir. 2014) (granting preliminary injunction against literally false claims to "ensure that the consuming public is able to make an informed decision based on accurate information").

Here, an injunction would benefit the public because it would prohibit Defendant from deceiving anyone who purchases its products and would correct the public statements Hologenix has already made. Defendant offers for sale "FDA determined" products, with the necessary implication that the FDA has made legal determinations about the products' performance and health benefits. Because Defendant's products have not been determined by the FDA to have any specific, concrete health benefits, Hologenix's false representations are causing potential customers and business partners to make decisions based on false information about the quality of Hologenix's products. Enjoining it from making such false representations would promote public safety.

III. This Court Should Enjoin Hologenix From Making FDA-Approved or FDA-Determined Claims and Compel It to Issue Corrective Advertising

Hologenix's false advertising is harming and will continue to harm MET, and only injunctive relief can allay that harm. The proper scope of injunctive relief here is twofold and well within the Court's discretion to issue. *United States v. AMC Entm't, Inc.*, 549 F.3d 760, 775 (9th Cir. 2008) (*citing Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (holding that the court has discretion to issue a preliminary injunction so long as the relief is "no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs"). First, the Court should enjoin Hologenix from making any statements, on any platform, that suggest that the FDA has approved Celliant or has made any determination about Celliant's benefits.

But because Hologenix's prior false statements have led third parties,

including Under Armour, American Textile, and the national media, to repeat the false claims, more here is necessary. The Court should require Hologenix to issue corrective advertising—on its website, its Facebook account, and its Twitter account, as well as issuing corrections to each and every media company that has written about Celliant. Corrective advertising is "appropriate to remedy consumer confusion caused by false advertising messages." *Healthport Corp. v. Tanita Corp. of Am.*, 563 F. Supp. 2d 1169, 1182 (D. Or. 2008), *aff'd*, 324 F. App'x 921 (Fed. Cir. 2009) (collecting cases).

To stop the ongoing harm caused by Hologenix's false statements, MET respectfully requests that the Court issue an injunction requiring the following corrective advertising.

First, ordering Hologenix to send the following statement to each and every manufacturer that has used Celliant in its products since July 25, 2017:

"Celliant has previously claimed that its product had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. The FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits.

Please state on your website where you offer products that use Celliant, and send a notice to any consumer lists where you have sent a prior notice regarding Celliant, that: 1) prior statements that the FDA had 'approved' Celliant or made a 'determination' about its benefits were false and 2) the FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

Second, ordering Hologenix to place the following statement on the landing page of the Celliant website, above any other text and in a font equal to or larger than any other text that appears on the website:

"Celliant has previously claimed that its product had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These

statements were false. The FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

Third, ordering Hologenix to issue the following statement once per day on its Facebook account and its Twitter account every day until this litigation is concluded:

"Celliant has previously claimed that its product had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. The FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

Fourth, ordering Hologenix to issue a press release with the following statement:

"Celliant has previously claimed that its product had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. The FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

Finally, ordering Hologenix to issue to each and every journalist that wrote an article about Celliant, including but not limited to those cited in this memorandum of law, the following:

"Hologenix LLC seeks a correction to your article of [Date] regarding Celliant. The article stated that Celliant had been 'approved' by the FDA and that the FDA had 'determined' Celliant provided certain benefits. These statements were false. Please issue a correction noting that the FDA has not approved Celliant for any purpose and has not made any determination about its purported benefits."

CONCLUSION

For the reasons stated above, MET respectfully requests that this Court enjoin Hologenix from making false and misleading statements about Celliant and order Hologenix to issue corrective statements on its website and social media platforms, and to media outlets that have repeated the false and misleading

statements.

Respectfully submitted,

Dated: April 22, 2019

MANATT, PHELPS & PHILLIPS, LLP

By: */s/ Barry W. Lee*
Barry W. Lee (Cal. Bar No. 088685)
blee@manatt.com
Jeffrey S. Edelstein (*pro hac vice*)
11355 W. Olympic Boulevard
Los Angeles, CA 90064
Telephone: (310) 312-4000

Attorneys for Plaintiff
Multiple Energy Technologies LLC